

**Remarks**

This Amendment is in response to the Final Office Action dated **January 22, 2009**. In the Final Office Action, claims 1-10, 13-15, 27, 48, 50, 54, and 55 were rejected under 35 USC 102(b) as being anticipated by Houser et al. (6,149,681); claim 11 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rudakov et al. (6,451,050); claim 12 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rudakov et al. (6,451,050) and Helmus et al. (2002/0033477); claims 16 and 21-26 were rejected under 35 U SC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Golds et al. (6,001,125); claim 17 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Buirge et al. (5,693,085); claim 18 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Yan (6,240,616); claims 19 and 20 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rhodes (5,665,117); claims 49 and 51 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Yang (2002/0062147); and claims 52 and 53 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Wang et al. (6,458,867).

**Amendments**

To further prosecution, Applicants have amended the specification; amended claims 1, 4-8, 13, 26-27; and cancelled claims 15-18, 23-25 and 54-55 without prejudice. Support for the specification as amended can be found at least in Figs. 2-3 of the application as filed. Support for the amendments to the claims can be found at least in paragraphs [0060]; [0062] and Figs. 2-6 of the application as filed. No new matter was added.

**35 USC 102**

In the Final Office Action, claims 1-10, 13-15, 27, 48, 50, 54, and 55 were rejected under 35 USC 102(b) as being anticipated by Houser et al. (6,149,681).

**Independent claim 1**

Independent claim 1 recites in part "a composite device ... comprising: a first liner ... a second liner ... the first liner extending from the first surface to the second liner ... to form

at least one pocket ... each pocket having a fluid containing a bioactive agent disposed therein.”

The Final Office Action asserted that “Houser et al. discloses the ... claimed invention as shown in Figure 42 ... and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 3, lines 41-52).”

Under Federal Circuit case law, anticipation requires that one embodiment disclose each and every element of the claim:

We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claims and, thus, cannot anticipate under 35 U.S.C. §102  
(*Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008))

Applicant notes that column 3, lines 41-52 of Houser is a portion of the Summary of the Invention and does not reference a particular figure. Applicant also notes that column 3, lines 41-52 of Houser refers to a pocket. A pocket is not discussed in reference to Fig. 42 of Houser (see col. 13, lines 9-19). A pocket is only discussed in reference to Fig. 16 of Houser (see e.g. col. 10, lines 46-50). Because Fig. 42 of Houser does not disclose a pocket containing a bioactive agent as recited in claim 1, Applicant submits that Houser does not teach each and every element of independent claim 1.

Moreover, as discussed previously, Fig. 16 of Houser does not disclose a first liner and a second liner where the first liner extends to the second liner to form at least one pocket, as recited in claim 1. Applicant further submits that neither Fig. 16 nor Fig. 42 of Houser discloses a solid segment having a trapezoidal cross-section as recited in claim 1. Applicant also submits that Houser does not disclose a pocket being pre-treated with a surfactant before the fluid is disposed therein. Additionally, Applicant submits that Houser does not disclose a first liner that is bioabsorbable and a second liner that is made from ePTFE having an internodal distance of about 5 microns to about 10 microns.

For at least these reasons, Applicant submits that Houser does not teach each and every element of independent claim 1. Because Houser does not anticipate claim 1, Applicant requests withdrawal of the rejection and submits that claim 1, and claims 2-10, 13-14, and 48 dependent therefrom, are in condition for allowance.

Independent claim 27

Independent claim 27 recites in part “[a] composite intraluminal device ... comprising: an elongate stent ... a first liner ... a second liner ... said second liner being directly joined to said first liner through said stent openings to form at least one pocket ... having a fluid containing a bioactive agent.”

As discussed above, Applicant submits that Fig. 42 of Houser does not disclose at least one pocket having a fluid containing a bioactive agent, as recited in claim 27 and that Fig. 16 does not disclose a second liner being directly joined to a first liner to form at least one pocket, as recited in claim 27. Thus, Applicant submits that neither Fig. 42 nor Fig. 16 anticipates claim 27.

Applicant further submits that neither structural layer 156 of Fig. 16 nor support structure 248 of Fig. 42 of Houser is disclosed as being a stent as recited in claim 27. Additionally, as discussed above, Houser does not disclose a solid segment having a trapezoidal cross-section as recited in claim 27; a pocket being pre-treated with a surfactant before the fluid is disposed therein; or a first liner that is bioabsorbable and a second liner that is made from ePTFE having an internodal distance of about 5 microns to about 10 microns.

For at least these reasons, Applicant submits that Houser does not teach each and every element of independent claim 27. Because Houser does not anticipate claim 1, Applicant requests withdrawal of the rejection and submits that claim 27, and claim 50 dependent therefrom, are in condition for allowance.

**35 USC 103 – Houser and Rudakov**

In the Final Office Action, claim 11 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rudakov et al. (6,451,050).

Claim 11 depends upon independent claim 1. As discussed above, Houser does not anticipate claim 1. The Final Office Action asserted that “Rudakov et al teaches a stent where the bioactive agent is encapsulated in a polymeric matrix.” Applicant submits that the asserted teaching of a bioactive agent encapsulated in a polymeric matrix by Rudakov does nothing to address the failure of Houser to teach each and every element of independent claim 1. For at least this reason, Applicant submits that the combination of Houser and Rudakov does not render claim

11 obvious.

Applicant requests withdrawal of the rejection and submits that claim 11 is in condition for allowance.

**35 USC 103 – Houser, Rudakov and Helmus**

In the Final Office Action, claim 12 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rudakov et al. (6,451,050) and Helmus et al. (2002/0033477).

Claim 12 depends upon claim 11. As discussed above, the combination of Houser and Rudakov does not render claim 11 obvious. The Final Office Action asserted that “Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix.” Applicant submits that the asserted teaching of a biological prosthesis that uses microparticles in the matrix by Helmus does nothing to address the failure of the combination of Houser and Rudakov to teach each and every element of claim 11. For at least this reason, Applicant submits that the combination of Houser, Rudakov and Helmus does not render claim 12 obvious.

Applicant requests withdrawal of the rejection and submits that claim 12 is in condition for allowance.

**35 USC 103 – Houser and Golds**

In the Final Office Action, claims 16 and 21-26 were rejected under 35 U SC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Golds et al. (6,001,125).

As discussed above, Houser does not teach each and every element of independent claims 1 and 27. Independent claim 1 recites in part “a second liner ... made from e PTFE having an internodal distance of about 5 microns to about 10 microns.” Independent claim 27 recites in part “a first liner ... being formed of ePTFE having an internodal distance of about 5 microns to about 10 microns.”

The Final Office Action asserted that “Golds et al. teaches a vascular graft constructed from porous ePTFE.” Applicant notes that Golds discloses an inner tube with an IND of between 40-100 microns and an outer tube with an IND of 15-35 microns. However, Applicant submits that Golds does not disclose a first liner that is bioabsorbable and a second liner

that is made from ePTFE having an internodal distance of about 5 to about 10 microns, as recited in claim 1. Applicant further submits that Golds does not disclose a first liner that forms an inner surface of the device and is formed of ePTFE having an internodal distance of about 5 microns to about 10 microns and a second liner that forms an outer surface of the device and is bioabsorbable as recited in claim 27.

For at least this reason, Applicant submits that the combination of Houser and Golds does not render independent claims 1 and 27 obvious. Applicant requests withdrawal of the rejection and submits that claims 1 and 27 are in condition for allowance.

### **35 USC 103 – Houser and Buirge**

In the Final Office Action, claim 17 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Buirge et al. (5,693,085).

As discussed above, claim 17 has been cancelled without prejudice, thereby mooted the instant rejection.

### **35 USC 103 – Houser and Yan**

In the Final Office Action, claim 18 was rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Yan (6,240,616).

The Final Office Action asserted that “Yan teaches a biological prosthesis that uses a bioabsorbable polymer to construct the device in col. 9, lines 22-36.” As discussed above, Applicant has cancelled claim 18. As further discussed above, Houser does not teach each and every element of independent claims 1 and 27. Independent claim 1 recites in part “a first liner ... being bioabsorbable.” Independent claim 27 recites in part “a second liner ... being bioabsorbable.”

Applicant disagrees that the coating 100 of Yan is a liner as recited in instant claims 1 and 27. MPEP §2111 states that “[d]uring patent examination, the pending claims must be “given their broadest reasonable interpretation *consistent with the specification*” (emphasis added). Fig. 1 of the instant application illustrates a liner 14,16 as recited in claims 1 and 27:

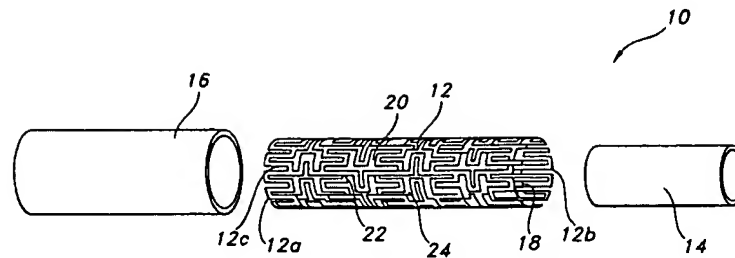
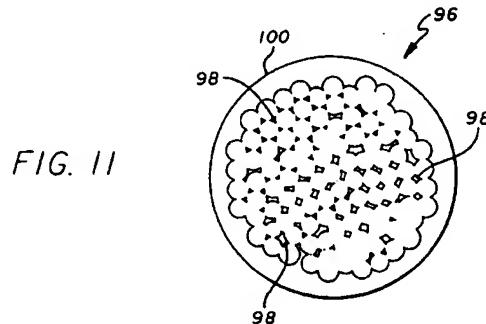


FIG. 1

In contrast, Fig. 11 of Yan is a cross-sectional view of a stent wire or strut that has a coating 100 (col. 8, lines 16-22):



Applicant also notes that claim 1 further recites “the first liner extending from the first surface to the second liner where the liners are directly bonded at a location coextensive with the second surfaces of the solid segments to form at least one pocket” and claim 27 further recites said second liner being directly joined to said first liner through said stent openings to form at least one pocket.” Applicant submits that Yan does not disclose a first liner directly bonded or joined to a second liner.

Based on the above, Applicant submits that Yan does not disclose a liner as recited in claims 1 and 27. For at least this reason, Applicant submits that the combination of Houser and Yan does not render independent claims 1 and 27 obvious. Applicant requests withdrawal of the rejection and submits that independent claims 1 and 27 are in condition for allowance.

**35 USC 103 – Houser and Rhodes**

In the Final Office Action, claims 19 and 20 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Rhodes (5,665,117).

Claims 19 and 20 depend upon independent claim 1. As discussed above, Houser does not teach each and every element of claim 1. The Final Office Action asserted that “Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device.” Applicant submits that the asserted teaching of a biological prosthesis of stainless steel or tantalum by Rhodes does nothing to address the failure of Houser to teach each and every element of claim 1. For at least this reason, Applicant submits that the combination of Houser and Rhodes does not render claims 19 and 20 obvious.

Applicant requests withdrawal of the rejection and submits that claims 19 and 20 are in condition for allowance.

**35 USC 103 – Houser and Yang**

In the Final Office Action, claims 49 and 51 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Yang (2002/0062147).

Claim 49 depends upon independent claim 1 and claim 51 depends upon independent claim 27. As discussed above, Houser does not teach and every element of claim 1 and does not teach each and every element of claim 27. The Final Office Action asserted that “Yang teaches a biological prosthesis that uses a gel to contain the biological agent.” Applicant submits that the asserted teaching of a gel by Yang does nothing to address the failure of Houser to teach each and every element of claim 1 and of claim 27. For at least this reason, Applicant submits that the combination of Houser and Yang does not render claims 49 and 51 obvious.

Applicant requests withdrawal of the rejection and submits that claims 49 and 51 are in condition for allowance.

**35 USC 103 – Houser and Wang**

In the Final Office Action, claims 52 and 53 were rejected under 35 USC 103(a) as being unpatentable over Houser et al. (6,149,681) in view of Wang et al. (6,458,867).

As discussed above, claims 52 and 53 have been cancelled without prejudice. As

further discussed above, Houser does not teach each and every element of independent claims 1 and 27. Independent claim 1 recites in part “each pocket being pre-treated with a surfactant before the fluid is disposed [in the pocket].” Independent claim 27 recites in part “the pocket being pre-treated with a surfactant to aid in incorporating the fluid into the pocket.”

The Final Office Action asserted that “Wang et al. teaches pre-treating medical devices in col. 12, lines 8-24 for purpose of reducing any irritation caused by the device.” Applicant submits that the asserted teaching of pre-treating a medical device by Wang does nothing to address the failure of Houser to teach each and every element of claim 1 and of claim 27. For at least this reason, Applicant submits that the combination of Houser and Wang does not render independent claims 1 and 27 obvious.

Applicant requests withdrawal of the rejection and submits that independent claims 1 and 27 are in condition for allowance.



**Conclusion**

Based on at least the above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-14, 19-20, 22, 26-27, and 48-51 is requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: May 22, 2009

By: / Jennifer L. Buss /  
Jennifer L. Buss  
Registration No.: 57321

6640 Shady Oak Rd., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001

f:\wpwork\jlb\14480us01\_amd\_20090513.doc